VIVOXID

510(k) Summary

OCT 19 2007

Submitter: Vivoxid Ltd.
Turku, Finland

Contact Information: Constance G. Bundy
C. G. Bundy Associates, Inc.
6470 Riverview Terrace
Fridley, MN 55432

Submission Date: July 10, 2007

Device Name and Classification: BonAlive™ Granules and Plates

Product Code: KKY
Class II per 21 CFR 878.3500
[redacted]

Equivalent Device Identification: Porous HDPE Surgical Implants, K022665
PerioGlas® Bone Graft Particulate, K053387

Device Description: BonAlive™ products are sterile medical devices made of S53P4 bioactive glass. Bioactive glasses are characterised by their ability to attach firmly to living tissue. Other properties include being able to guide tissue growth, bond chemically with surrounding bone in an implantation bed and promote new bone formation in the implanted area. It has been shown that tissue bonds to bioactive glass due to formation of a silica-gel layer on the glass. The silica-rich layer acts as a template for a calcium phosphate precipitation, which then bonds the bioactive glass to the surrounding bone. This makes the bioactive glass a unique material for filling defects and replacing damaged bony tissue. The composition of this synthetic, osteoconductive and bacterial-growth inhibiting material is, by weight, SiO_2 53%, Na_2O 23%, CaO 20% and P_2O_5 4%. BonAlive™ products are supplied as granules and plates. Both are bone grafting materials intended to fill, augment, or reconstruct bony defects of the cranial and maxillofacial region. BonAlive™ granules and plates are sterilized in hot dry air. The granules are available as different granule and unit sizes. The plates are available in different shapes and sizes.

Intended Use: BonAlive™ Granules and BonAlive™ Plate are intended for the augmentation or reconstruction of the cranio-maxillofacial skeleton.

Comparison Table:

Descriptive Information	BonAlive™ granules and plates	Porous HDPE Surgical Implants, K022665	PerioGlas Bone Graft Particulate, K053387
Intended Use	BonAlive™ Granules and BonAlive™ Plate are intended for the augmentation or reconstruction of the cranio-maxillofacial skeleton.	Porous HDPE Surgical Implants are intended for the augmentation or reconstruction of the cranio-maxillofacial areas.	Same as BonAlive device
Material and properties	S53P4 Bioactive Glass - synthetic, osteoconductive, bacterial growth inhibiting	Alloplastic, porous high density polyethylene (HDPE)	45S5 Bioactive Glass - same properties as BonAlive
Product Form	Granules and plates	Block, sheet, anatomical shapes	Particulates
Mode of Action	Tissue bonds to the bioactive glass due to the formation of a silica-gel layer on the glass. The silica-rich layer acts as a template for a calcium phosphate precipitation, which bonds the bioactive glass to the surrounding bone.	The porous HDPE allows for bony tissue ingrowth into its pores	Same as BonAlive device
Resorption Rate	Slowly, over a period of years	Not applicable	Six months
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Sterilization Method	Hot, dry air	Sterile	EtO

Summary of Perfomance Testing of Bioactive Glass (BAG) S53P4, BonAlive™:
Preclinical testing included biocompatibility, solubility, surface structure and dissolution. The amounts of Si and P released from BAG were extremely low indicating a good stability and safety of this material for clinical use in frontal sinus obliteration. The amount of calcium (Ca) released from the material seems to create a suitable environment for formation of calcium phosphate layer that is prerequisite for new bone formation. The biocompatibility tests showed the device was safe for the intended uses.

In animal studies BAG produced more and faster new bone than did the hydroxyl apatite that was used as a control. Proper blood circulation in the periosteum flap at early stage predisposed the healing process with both materials. The healing process proceeded after the connective tissue phase to obliteration of bone cavity both in animal and in human clinical studies.

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Clinically BAG is well functioning, stable, safe and well tolerated glass material that creates suitable local environment for permanent filling of frontal sinuses. Remnants of glass particles found in the bony filling seem to maintain the achieved bone formation and closure of sinuses. The healing process and stability of the clinical outcome in sinuses could be assessed reliably by using the ROI assessments.

In patients with orbital floor fractures the orbital floor prostheses manufactured from BAG have been well functioning and well tolerated. The same conclusion can be made on the use of BAG in septum perforations and narrowing of the nasal cavity. The material itself has not caused any harmful reactions during the clinical follow-up period.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vivoxid Ltd.
% C.G. Bundy Associates, Inc.
Ms. Constance G. Bundy
6470 Riverview Terrace
Fridley, Minnesota 55432

OCT 19 2007

Re: K071937
Trade/Device Name: BonAlive™ Granules and BonAlive™ Plates
Regulation Number: 21 CFR 878.3500
Regulation Name: Polytetrafluoroethylene with carbon fibers composite implant material
Regulatory Class: II
Product Code: KKY
Dated: October 1, 2007
Received: October 4, 2007

Dear Ms. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K071937

Device Name: BonAlive™ Granules and BonAlive™ Plates

Indications for Use:

BonAlive™ Granules and BonAlive™ Plate are intended for the augmentation or reconstruction of the cranio-maxillofacial skeleton.

Prescription Use ____X___
(Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071937